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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,671	06/25/2003	James Roy Maxwell	1391/1555	4734

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,671	MAXWELL ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *42-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41 and 71-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment, response, Terminal Disclaimer, IDS and declaration filed on April 3, 2006 has been received and entered into the case. Claims 71 – 74 are added, claims 1 – 74 are pending; claims 42 – 70 are withdrawn from consideration; claims 1 – 41 and 71 – 74 have been considered on the merits. All arguments, the declaration and IDS have been fully considered.

Claim Objections

1. Claims 71 – 74 are objected to because of the following informalities: The abbreviated terms "P. gingivalis" and "F. nucleatum" should first be spelled out followed by the abbreviated term in parenthesis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 – 41 and 71 – 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification as originally filed, in such a way as to reasonably convey to

one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a pullulan free edible film comprising an amount of magnolia Bark extract such that the composition provides a concentration of greater than about 3.0 micrograms per milliliter of saliva in the oral cavity of a user. However, the specification fails to teach or disclose such an amount of what appears to be MBE per ml saliva. The specification does teach the MBE has a MIC of particular amounts (spec, page 4), however the specification does not teach a film that provides a particular concentration per ml of saliva. This is a new matter rejection.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 – 41 and 71 – 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents and 71 – 74 are drawn to an edible film, however are rendered vague and indefinite for reciting about 3.0, 3.9, and/or 7.8 micrograms, because it is unclear to what the amount refers. For example, it is unclear if the compositions provide the amounts relative to a film forming agent or MBE. For purposes of examination, the claims have been interpreted to mean the composition provides the amounts of MBE.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 41 and 71 – 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow (WO 02/43657 A2) in view of Nanba and/or Scherl.

Applicant claims a pullulan free edible film composition comprising an effective amount of a film forming agent and an effective amount of a MBE such that the composition provides greater than about 3.0 ug/ml saliva in the oral cavity of the user. The film forming agent comprises a mixture of maltodextrin, filler and hydrocolloid; the maltodextrin comprises 5 – 60% or 20 – 40% of the film; the hydrocolloid comprises 10 – 50% or 20 – 30% of the film; the filler comprises 5 – 30% or 15 – 25% of the film. The hydrocolloid is selected from natural

gums, biosynthetic gums, natural seaweeds, natural plant extrudates, natural fiber extracts, gelatin, processed starch, cellulosic materials, alginates, pectin and combinations thereof; natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthum gum; sodium alginate or calcium alginate; or a carrageenan. The filler is a food grade bulk filler selected from microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay, talc, titanium dioxide, calcium phosphates and combinations thereof; wood; magnesium or aluminum silicates or combinations thereof; mono-calcium phosphate, di-calcium phosphate, tri-calcium phosphate or combinations thereof. The magnolia bark extract is about 1 – 10%, 8% 5% of the film; and comprises magnolol and/or honokiol. The composition further comprises an effective amount of a medicament that is that is an oral cleansing, breath freshening agent selected from pH control agents, inorganic components for tartar/caries control, breath freshening agents, anti-plaque agents, anti-gingivitis agents, saliva stimulating agents, pharmaceutical agents, nutraceutical agents, vitamins, mineral and combinations thereof. Specifically, the medicament is urea; phosphates or fluorides; zinc gluconate; chlorhexidene, CPC, triclosan or combinations thereof; a food acid selected from citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof. The composition further comprising a softening agent at about 0 – 20% or 2 – 10%; and is selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof. The composition further comprises a coloring agent; a flavoring agent at at 0.1 – 20% or 10 – 15%. The flavoring is selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties and combinations thereof; oils of citrus, peppermint, spearmint, mint, clove, wintergreen and combinations thereof; menthol, eucalyptus,

thymol and combinations thereof. The composition further comprises an effective amount of emulsifier; that is selected from lecithin, (c10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monosteerate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof. Applicant additionally claims a pullulan free edible film comprising an effective amount of a film forming agent and an effective amount of MBE for reducing bacterial concentrations of P. gingivalis and F. nucleatum in the oral cavity of the user, such that the composition provides a concentration of MBE greater than about 3.0 ug/ml saliva. The composition provides greater than 3.9ug/ml saliva against P. gingivalis; 3.9 or 7.8 um/ml saliva against F. nucleatum.

Barklalow teaches a pullulan free edible film comprising a film forming agent, filler, plasticizing agent (softener), medicaments and additives for treating halitosis, plaque, or gingivitis (abstract). The film forming agent is present at 10 – 90% and is selected from cellulose ether, modified starches, natural gums, polymers, hydrocolloids, seaweed, land plant extrudates and combinations thereof (p.2), gum arabic, guar gum, carageenan gum, ghatti, xanthum gum, locust gum and combinations thereof (p.6), alginates and/or pectin (p.7). The filler is present at 10 – 90% and is selected from magnesium carbonate, calcium carbonate, calcium phosphate, magnesium and calcium silicates, limestone, clay, talc, titanium dioxide, microcrystalline cellulose, cellulose polymers, wood and combinations thereof (p.7). The plasticizing agent is present at about 0 – 20 or 2 – 8% and is selected from sorbitola, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup and combinations thereof (p.7-8). The film further comprises a medicament selected from pH

control agents, oral care agents, breath freshening agents, pharmaceutical agents, nutraceutical agents, saliva stimulating agents, vitamins, mineral and combinations thereof, urea, caries control agents, phosphates, fluorides, chlorohexidene, CPC, triclosan, citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof, zinc gluconate, oils of citrus, peppermint, spearmint, mint, clove, wintergreen, anise and menthol (p.8-9). Other additives include coloring agents, flavoring agents and emulsifiers (p.9). The flavors are present at 0.1 – 20% or 10 – 15% and may be selected from essential oils, synthetic flavors, flavors derived from fruit (p.9). Emulsifiers may include hydrogenated vegetable oils (p.10) and/or lecithin (examples 1-12). The compositions further comprise maltodextrin (examples 1 – 4).

Barkalow does not teach the film wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; wherein the claimed amounts of magnolia bark extract are present, or wherein the film provides the claimed amounts to the oral cavity against the claimed bacteria. However Barkalow does teach the medicaments may be agents for preventing dental caries, anti-plague agents, and/or anti-gingivitis agents. At the time of the claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolol and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scherl teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). Scherl further teaches the compositions are effective against F. nucleatum (see examples). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scherl, to include magnolia bark extract in the film of Barkalow, since it was a well known agent for preventing dental

caries, plague and gingivitis, as evidenced by Nanba and Scherl. In addition, since such medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract in the film of Barkalow (thus also the concentration administered), with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

Barkalow does not teach each of the claimed ingredients in the claimed amounts. However, since such ingredients and additives are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of film forming agents in the film of Barkalow, with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

Finally, although the references do not identify the compositions are effective against P. gingivalis, they each teach the compositions are useful for treating gingivitis. Since it was known in the art that P. gingivalis is the most common organism strongly associated with gingivitis, one in the art would have recognized that the instant compositions would be effective against P. gingivalis.

9. Claims 1 – 41 and 71 – 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zyck (US 6740332) in view of Nanba and/or Scherl.

Applicant claims a pullulan free edible film composition comprising an effective amount of a film forming agent and an effective amount of a MBE such that the composition provides greater than about 3.0 ug/ml saliva in the oral cavity of the user. The film forming agent

comprises a mixture of maltodextrin, filler and hydrocolloid; the maltodextrin comprises 5 – 60% or 20 – 40% of the film; the hydrocolloid comprises 10 – 50% or 20 – 30% of the film; the filler comprises 5 – 30% or 15 – 25% of the film. The hydrocolloid is selected from natural gums, biosynthetic gums, natural seaweeds, natural plant extrudates, natural fiber extracts, gelatin, processed starch, cellulosic materials, alginates, pectin and combinations thereof; natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthum gum; sodium alginate or calcium alginate; or a carrageenan. The filler is a food grade bulk filler selected from microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay, talc, titanium dioxide, calcium phosphates and combinations thereof; wood; magnesium or aluminum silicates or combinations thereof; mono-calcium phosphate, di-calcium phosphate, tri-calcium phosphate or combinations thereof. The magnolia bark extract is about 1 – 10%, 8% 5% of the film; and comprises magnolol and/or honokiol. The composition further comprises an effective amount of a medicament that is that is an oral cleansing, breath freshening agent selected from pH control agents, inorganic components for tartar/caries control, breath freshening agents, anti-plaque agents, anti-gingivitis agents, saliva stimulating agents, pharmaceutical agents, nutraceutical agents, vitamins, mineral and combinations thereof. Specifically, the medicament is urea; phosphates or fluorides; zinc gluconate; chlorhexidene, CPC, triclosan or combinations thereof; a food acid selected from citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof. The composition further comprising a softening agent at about 0 – 20% or 2 – 10%; and is selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof. The composition further comprises a coloring agent; a flavoring agent at

at 0.1 – 20% or 10 – 15%. The flavoring is selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties and combinations thereof; oils of citrus, peppermint, spearmint, mint, clove, wintergreen and combinations thereof; menthol, eucalyptus, thymol and combinations thereof. The composition further comprises an effective amount of emulsifier; that is selected from lecithin, (c10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monosteerate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof. Applicant additionally claims a pullulan free edible film comprising an effective amount of a film forming agent and an effective amount of MBE for reducing bacterial concentrations of P. gingivalis and F. nucleatum in the oral cavity of the user, such that the composition provides a concentration of MBE greater than about 3.0 ug/ml saliva. The composition provides greater than 3.9ug/ml saliva against P. gingivalis; 3.9 or 7.8 um/ml saliva against F. nucleatum.

Zyck teaches pullulan free, edible films comprising maltodextrins, hydrocolloids and fillers (abstract). The films further comprise medicaments and other additives for providing oral care, cleansing and breath freshening (abstract), to include softeners, colorants, flavors and emulsifiers (col.3 line 1-10). The maltodextrin is present at about 5 – 60 or 20 – 40%, the hydrocolloid is present at about 10 – 50% or 20 – 30% and the filler is present at about 5 – 30% or 15 – 20% (col.3-4). Hydrocolloids are selected from natural seaweeds, natural seed gums, natural plant extrudates, natural fiber extracts, biosynthetic gums, gelatins, processed starch, cellulose materials, alginates, sodium alginate, calcium alginate, carrageenans, guar gum, locust gum, tara gum, gum Arabic, ghatti hum agar gum, xanthum gum, pectin, and combinations

thereof (col.3 line 50-63). Fillers include microcrystalline cellulose, cellulose polymers, wood, magnesium and calcium carbonate, ground limestone, silicates such as magnesium and aluminum, clay, talc, titanium dioxide, mono, di, and/or tri-calcium phosphates (col.3 line 64 – col.4 line 8). Medicaments include oral cleansing, breath freshening agent selected from pH control agents, urea, inorganic components for tartar/caries control, phosphates, fluorides, breath freshening agents, zinc gluconate, anti-plaque agents, anti-gingivitis agents, chlorhexidene, CPC, triclosan, saliva stimulating agents, food acid, citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, and/or tartaric acids, pharmaceutical agents, nutraceutical agents, vitamins, minerals or combinations thereof (col.4 cline 19-34). Softening agents are present at about 0 – 20% or 2 – 10% and are selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof (col.4 line 52-61). Flavoring agents are present at about 0.1 – 20% or 10 – 15% and are selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties, oils of citrus, peppermint, spearmint, mint, clove, wintergreen, menthol, eucalyptus, thymol and combinations thereof (col.5 line 1-12). The emulsifiers are selected from lecithin, (C10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monosteerate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof (col.5 line 13-22)

Zyck does not teach the film wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; or wherein the claimed amounts of magnolia bark extract are present; or wherein the film provides the claimed amounts to the oral cavity against the claimed bacteria. However Zyck does teach the medicaments may be

agents for preventing dental caries, anti-plague agents, and/or anti-gingivitis agents. At the time of the claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolo and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scherl teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). Scherl further teaches the compositions are effective against F. nucleatum (see examples). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scherl, to include magnolia bark extract in the film of Zyck, since it was a well known agent for preventing dental caries, plague and gingivitis, as evidenced by Nanba and Scherl. In addition, since such medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract in the film of Zyck, with a reasonable expectation for successfully obtaining the effective edible film of Zyck.

Finally, although the references do not identify the compositions are effective against P. gingivalis, they each teach the compositions are useful for treating gingivitis. Since it was known in the art that P. gingivalis is the most common organism strongly associated with gingivitis, one in the art would have recognized that the instant compositions would be effective against P. gingivalis.

Double Patenting

Rejections under the judicially created doctrine of obviousness-type double patenting have been withdrawn due to submission of a Terminal disclaimer on April 3, 2006.

Response to Arguments

Applicant argues that the limitations of providing 3.0, 3.9 or 7.8 ug MBE /ml saliva are not taught by the prior art. Applicant additionally argues that the instant composition is particularly effective because the MBE is active in human saliva. Applicant provides a declaration in support of this assertion.

However, these arguments and declarations fail to persuade for the following reasons. As stated in the above rejection, MBE was clearly known in the art to be effective against gingivitis (or P.gingivalis), dental caries, plaque, and F. nucleatum, as evidenced by Nanba and Scherl. Furthermore, the references each demonstrate that the films and active agents are effective in the oral cavity of the user, or are effective in human saliva. Thus, the declaration does not provide evidence that it is unexpected that MBE is active in human saliva. In addition, it is reiterated that MBE is recognized as the active ingredient and is therefore a result effective variable. Moreover, a person of ordinary skill in the art would have been motivated by standard practice and experimentation to optimize the amount of MBE used in the film with a reasonable expectation for successfully obtaining an effective edible film.

The claims are rejected for these reasons and those stated in the rejections above.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 21, 2006
AU 1651

RUTH A. DAVIS
PATENT EXAMINER